

SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
EXAMINING GROUP 1614  
Patent Application  
Docket No. NPB-100D5  
Serial No. 09/970,558

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Dwayne Jones

Art Unit : 1614

Applicant(s) : David A Carver, Timothy Prout, Hernita Ewald, Robyn Elliott, Paul Handreck

Serial No. : 09/970,558

Filed : October 4, 2001

For : Injectable Composition

Assistant Commissioner for Patents  
Washington, D.C. 20231

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §§ 1.97 AND 1.98

Sir:

Applicants wish to bring to the attention of the Examiner litigation involving patents relating to the pending patent application. Applicants' assignee, NaPro Biotherapeutics, is currently a Plaintiff in Abbott Laboratories and NaPro Biotherapeutics v. Mylan Laboratories, *et al.*, C.A. No. 01-CV-1048, pending in the U.S. District Court for the Western District of Pennsylvania. The U.S. Patents that are the subject of this case are U.S. Patents No. 5,733,888; No. 5,972,164; No. 6,140,359; and No. 6,306,894. In this action, Plaintiffs have alleged that Defendants infringe one or more claims of the patents in suit. Applicants have attached a list of pleadings that have been submitted to the Court in this case at Exhibit R2.

Applicants note that they do not believe that they have received material information they are obligated to disclose in the course of this litigation, but wish to bring the litigation to the attention of the examiner in an abundance of caution.

Defendants have asserted several defenses in their amended answer and counterclaim, which

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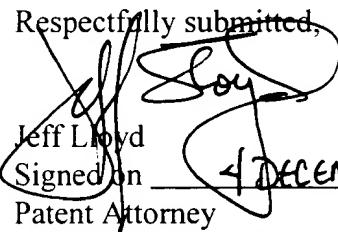
was filed on September 11, 2002 and is attached at Exhibit R4. Defendant alleges invalidity under 35 U.S.C. §§ 101, 102(a), 102(f), 102(g)(2), 103(a), 112, and 132. Plaintiffs dispute these claims. The Court in this case has not entered any ruling against Plaintiffs related to these allegations.

Defendants have also alleged the defense of inequitable conduct. Plaintiffs dispute this claim. The Court in this case has not entered any ruling against the Plaintiffs related to Defendants' inequitable conduct allegations. In part, Defendants have alleged that material information was contained in the answer filed and discovery responses served in the case of NaPro Biotherapeutics and Abbott Laboratories v. Bristol-Myers Squibb Co., Civil Action No. 00-CV-1818, U.S. District Court for the District of Colorado. Plaintiffs disputed the allegations contained in these pleadings and did not deem them to be material. The court did not enter any ruling against Plaintiffs in that litigation. This case is no longer pending and has settled out of court. A list of submissions made to the court in the Colorado litigation, and the answer and discovery response referred to by Mylan in the current litigation, are attached at Exhibits R3, R5 and R6.

Due to a Protective Order entered by the Court in the Mylan litigation, (Exhibit R1) Applicants are not permitted to provide the Examiner with confidential information, such as written discovery, deposition transcripts, or additional pleadings which were filed under seal.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Respectfully submitted,  
  
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JL/srp  
Enclosures as stated above